

PATENT

Appl. No. 10/763,379
Supp. Amdt. dated March 2, 2006
Reply to Office Action of October 21, 2005

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings of claims in the application:

Listing of Claims:

1. (previously presented) A topical delivery composition in a pressurized container, said composition comprising:
 - up to 15% w/w of at least one pharmaceutically active compound, or its pharmaceutically acceptable salt or a prodrug thereof, wherein at least one of said pharmaceutically active compounds is an antibiotic agent;
 - from about 83% to about 97.9% w/w of a quick-breaking foaming agent, wherein said quick-breaking foaming agent comprises a C₁-C₆ alcohol, a C₁₄-C₂₂ alcohol, water, and a surfactant; and
 - from about 2% to about 7% w/w of an aerosol propellant selected from the group consisting of a hydrocarbon, a chlorofluorocarbon, dimethyl ether, hydrofluorocarbons and a mixture thereof,
 - a pH-adjusting agent selected from the group consisting of an acid or a base; and
 - wherein said composition is a quick-breaking temperature sensitive foam after release from said container.
2. (canceled)
3. (previously presented) The composition of claim 1, wherein at least one of said pharmaceutically active compounds is clindamycin, or a pharmaceutically acceptable salt or a prodrug thereof.
4. (previously presented) The composition of claim 3, wherein said clindamycin is clindamycin phosphate.
5. (original) The composition of claim 1, wherein said at least one pharmaceutically active compound comprises a combination of active agents.

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6-9. (canceled)

10. (previously presented) The composition of claim 1, wherein the ratio of said C₁-C₆ alcohol to water is from about 1:7 to about 1:16.

11. (withdrawn) The composition of claim 10, wherein the ratio of said C₁-C₆ alcohol to water is about 1:7.

12. (withdrawn) The composition of claim 10, wherein the ratio of said C₁-C₆ alcohol to water is about 1:16.

13. (canceled)

14. (previously presented) The composition of claim 1, wherein the foam breaking temperature of said quick-breaking temperature sensitive foam is from about 30°C to about 36°C.

15. (previously presented) The composition of claim 1, wherein the ratio of said C₁-C₆ alcohol to water is about 1.7:1.

16. (previously presented) The composition of claim 1, wherein said surfactant is present in an amount of from about 0.1% to about 10 % w/w.

17. (original) The composition of claim 16, wherein said surfactant is selected from the group consisting of an ethoxylated non-ionic surfactant, an ethoxylated ionic surfactant, and a mixture thereof.

18. (original) The composition of claim 16, wherein said surfactant is a polysorbate.

19. (previously presented) The composition of claim 1, further comprising an emollient.

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20. (original) The composition of claim 19, wherein said emollient is a polyol.
21. (original) The composition of claim 20, wherein said polyol is selected from the group consisting of propylene glycol, glycerol, and a mixture thereof.
22. (previously presented) The composition of claim 1, wherein the amount of said C₁-C₆ alcohol in said quick-breaking foaming agent is from about 55% to about 65% w/w.
23. (original) The composition of claim 22, wherein said C₁-C₆ alcohol is selected from the group consisting of methanol, ethanol, propanol, butanol, and a mixture thereof.
24. (original) The composition of claim 23, wherein said C₁-C₆ alcohol is ethanol.
25. (original) The composition of claim 23, wherein said C₁-C₆ alcohol is a mixture of ethanol and at least one other C₁-C₆ alcohol.
26. (previously presented) The composition of claim 1, wherein the amount of said C₁₄-C₂₂ alcohol in said quick-breaking foaming agent is from about 1% to about 5% w/w.
27. (original) The composition of claim 26, wherein said C₁₄-C₂₂ alcohol is a C₁₄-C₂₀ alcohol.
28. (original) The composition of claim 27, wherein said C₁₄-C₂₀ alcohol is selected from the group consisting of cetyl alcohol, stearyl alcohol, and a mixture thereof.
29. (original) The composition of claim 28, wherein said C₁₄-C₂₀ alcohol is a mixture of cetyl alcohol and stearyl alcohol.

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30. (original) The composition of claim 29, wherein the ratio of cetyl alcohol to stearyl alcohol is from about 60:40 to about 80:20.

31. (original) The composition of claim 30, wherein the ratio of cetyl alcohol to stearyl alcohol is about 70:30.

32. (original) The composition of claim 1, wherein said composition comprises water in an amount up to 90% w/w.

33. (previously presented) The composition of claim 1, wherein said composition comprises water in an amount from about 30% to about 40% w/w.

34. (canceled)

35. (previously presented) The composition of claim 1 wherein the pH of said composition is from about pH 4.0 to about pH 9.0.

36. (previously presented) The composition of claim 1 wherein the pH of said composition is from about pH 4.0 to about pH 6.5.

37. (original) The composition of claim 1, wherein said composition comprises:
from about 0.1% to about 10% w/w of at least one pharmaceutically active compound, or its pharmaceutically acceptable salt or a prodrug thereof;
from about 83% to about 97.9% w/w of a quick-breaking alcoholic foaming agent; and
from about 2% to about 7% w/w of an aerosol propellant selected from the group consisting of a hydrocarbon, a chlorofluorocarbon, and a mixture thereof.

38-64. (canceled)

65. (previously presented) A topical delivery composition in a pressurized container, said composition comprising:

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up to 15% w/w of at least one antibiotic agent, or its pharmaceutically acceptable salt or a prodrug thereof;

from about 83% to about 97.9% w/w of a quick-breaking foaming agent, wherein said quick-breaking foaming agent comprises a C₁-C₆ alcohol, a C₁₄-C₂₂ alcohol, water, and a surfactant; and

from about 2% to about 7% w/w of an aerosol propellant selected from the group consisting of a hydrocarbon, a chlorofluorocarbon, dimethyl ether, hydrofluorocarbons and a mixture thereof,

wherein said composition is a quick-breaking temperature sensitive foam after release from said container.

66. (previously presented) The composition of claim 65, wherein said at least one antibiotic agent is clindamycin, or a pharmaceutically acceptable salt or a prodrug thereof.

67. (currently amended) The composition of claim 1, wherein the ratio of said C₁-C₆ alcohol to water is from about ~~[[1:5]]~~ 1.5:1 to about 1:16.

68. (currently amended) The composition of claim 67, wherein the ratio of said C₁-C₆ alcohol to water is ~~[[from]]~~ about ~~[[1.6]]~~ 1.6:1.

69. (previously presented) A topical delivery composition in a pressurized container, said composition comprising:

up to 15% w/w of at least one pharmaceutically active compound, or its pharmaceutically acceptable salt or a prodrug thereof, wherein at least one of said pharmaceutically active compounds is an antibiotic agent;

from about 83% to about 97.9% w/w of a quick-breaking foaming agent, wherein said quick-breaking foaming agent comprises a C₁-C₆ alcohol, a C₁₄-C₂₂ alcohol, water, and a surfactant;

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from about 2% to about 7% w/w of an aerosol propellant selected from the group consisting of a hydrocarbon, a chlorofluorocarbon, dimethyl ether, hydrofluorocarbons and a mixture thereof; and

wherein said composition is a quick-breaking temperature sensitive foam after release from said container.

70. (previously presented) The composition of claim 69, wherein at least one of said pharmaceutically active compounds is clindamycin, or a pharmaceutically acceptable salt or a prodrug thereof.

71. (previously presented) A topical delivery composition in a pressurized container, said composition comprising:

up to 15% w/w of at least one pharmaceutically active compound, or its pharmaceutically acceptable salt or a prodrug thereof, wherein at least one of said pharmaceutically active compounds is an antibiotic agent;

from about 83% to about 97.9% w/w of a quick-breaking foaming agent, wherein said quick-breaking foaming agent comprises a C₁-C₆ alcohol, a C₁₄-C₂₂ alcohol, water, and a surfactant, wherein said surfactant is present from 0% to 10% w/w;

from about 2% to about 7% w/w of an aerosol propellant selected from the group consisting of a hydrocarbon, a chlorofluorocarbon, dimethyl ether, hydrofluorocarbons and a mixture thereof; and

wherein said composition is a quick-breaking temperature sensitive foam after release from said container.

72. (previously presented) The composition of claim 71, wherein at least one of said pharmaceutically active compounds is clindamycin, or a pharmaceutically acceptable salt or a prodrug thereof.

73. (previously presented) A topical delivery composition in a pressurized container, said composition comprising:

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up to 15% w/w of at least one pharmaceutically active compound, or its pharmaceutically acceptable salt or a prodrug thereof, wherein at least one of said pharmaceutically active compounds is an antibiotic agent;

from about 83% to about 97.9% w/w of a quick-breaking foaming agent, wherein said quick-breaking foaming agent comprises a C₁-C₆ alcohol, a C₁₄-C₂₂ alcohol, water, and a surfactant;

an aerosol propellant selected from the group consisting of a hydrocarbon, a chlorofluorocarbon, dimethyl ether, hydrofluorocarbons and a mixture thereof, wherein the maximum amount of propellant is determined by its miscibility in said composition to form a homogeneous solution; and

wherein said composition is a quick-breaking temperature sensitive foam after release from said container.

74. (previously presented) The composition of claim 73, wherein at least one of said pharmaceutically active compounds is clindamycin, or a pharmaceutically acceptable salt or a prodrug thereof.

75. (New) A method for treating a bacteria-mediated disease, said method comprising:

applying a quick-breaking temperature sensitive foam composition to the skin of a subject in need thereof, wherein said composition is a composition of claim 1, said composition comprising:

up to 15% w/w of at least one pharmaceutically active compound, or its pharmaceutically acceptable salt or a prodrug thereof, wherein at least one of said pharmaceutically active compounds is an antibiotic agent;

from about 83% to about 97.9% w/w of a quick-breaking foaming agent, wherein said quick-breaking foaming agent comprises a C₁-C₆ alcohol, a C₁₄-C₂₂ alcohol, water, and a surfactant; and

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from about 2% to about 7% w/w of an aerosol propellant selected from the group consisting of a hydrocarbon, a chlorofluorocarbon, dimethyl ether, hydrofluorocarbons and a mixture thereof,

a pH-adjusting agent selected from the group consisting of an acid or a base; and wherein said composition is a quick-breaking temperature sensitive foam after release from said container.

76. (New) The method of claim 75, wherein said antibiotic agent is clindamycin.

77. (New) The method of claim 76, wherein said clindamycin is clindamycin phosphate.

78. (New) The method of claim 75, wherein said at least one pharmaceutically active compound comprises a combination of active agents.

79. (New) The method of claim 75, wherein the ratio of said C₁-C₆ alcohol to water is from about 1:7 to about 1:16.

80. (New) The method of claim 75, wherein the ratio of said C₁-C₆ alcohol to water is about 1:7.

81. (New) The method of claim 75, wherein the ratio of said C₁-C₆ alcohol to water is about 1:16.

82. (New) The method of claim 75, wherein the foam breaking temperature of said quick-breaking temperature sensitive foam is from about 30°C to about 36°C.

83. (New) The method of claim 75, wherein the ratio of said C₁-C₆ alcohol to water is about 1.7:1.

84. (New) The method of claim 75, wherein said surfactant is present in an amount of from about 0.1% to about 10 % w/w.

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85. (New) The method of claim 75, wherein said surfactant is selected from the group consisting of an ethoxylated non-ionic surfactant, an ethoxylated ionic surfactant, and a mixture thereof.

86. (New) The method of claim 75, wherein the ratio of said C₁-C₆ alcohol to water is from about 1.5:1 to about 1:16.

87. (New) The method of claim 75, wherein the ratio of said C₁-C₆ alcohol to water is about 1.6:1.

88. (New) The method of claim 75, wherein said bacteria-mediated disease is acne.

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